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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/913,967	12/31/2001	Wilhelmus Evergardu Hennink	313632001000	8024

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MORRISON & FOERSTER LLP  
12531 HIGH BLUFF DRIVE  
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EXAMINER

FUBARA, BLESSING M

ART UNIT

PAPER NUMBER

1618

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/913,967	HENNINK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 28 October 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 and 21-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 21-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt of request for extension of time, amendment, remarks and 1.132 declarations under 37 CFR. Claims 1-17 and 21-26 are pending. No claim amendment was submitted.

#### ***Claim Rejections - 35 USC § 102***

1. Claims 1-5, 7-10 and 13 remain rejected under 35 U.S.C. 102(b) as being anticipated by Okihara et al. (J. Macromol. Sci. Phys. (1991) B30 (1 & 2) 119-140, submitted on form PTO-1449).

Applicants argue that the product of Okihira cannot inherently be a hydrogel because water is required for the formation of hydrogel.

2. Applicants' arguments filed 10/28/05 have been fully considered but they are not persuasive.

The claim 1 is a composition claim. The oligomers are water-soluble and these oligomers are further defined by claim 2. Okihara discloses the oligomers recited in claim 2 and thus the Okihara oligomers are inherently water-soluble. The claims do not exclude organic solvent.

#### **The 1.132 declarations:**

The declaration stating that hydrogel cannot form in the absence of water is not commensurate with the claims because the claims have not excluded organic solvent. The oligomers of the claims and the prior art are water-soluble.

3. Claims 1-10, 14 and 21-26 remain rejected under 35 U.S.C. 102(b) as being anticipated by Hennink et al. (WO 98/00170, cited on form PTO-1449).

Applicants argue:

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a) “Hydrogels formed by free radical polymerization of a cross-linkable group contain covalent bond between the interpenetrating polymer networks, and are distinguishable from hydrogels formed through physical non-covalent interaction between chiral monomers of opposite chirality.”

b) The invention as claimed requires complimentary chiral groups on the polymers to interact.

4. Applicants' arguments filed 10/28/05 have been fully considered but they are not persuasive.

Regarding b) no specific chirality is claimed and the prior art meets the limitation of the oligomers recited in claim 2, which defines the oligomers of claim 1. A racemic molecule has equal components of each component of the opposite chirality. Regarding a), it is noted that no specific chirality is recited and the composition claims do not exclude or include covalent or non-covalent interaction. “When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). The rejection follows below.

Hennink discloses a biodegradable hydrogel that contains hydrolysable bonds and where the hydrogel consists of two interpenetrating polymer networks interconnecting to one another through hydrolysable spacers (abstract). In Hennink, (poly)glycolic acid and/or (poly)lactic acid spacers are introduced between polymerizable methacrylate groups and dextran (page 7, lines 24-27 and page 8). The hydrogel is prepared by a radical polymerization in the presence of tertiary amine and persulfate initiator (page 9, lines 14-23). Increasing degree of substitution (DS) yields a more cross-linked network (page 9, lines 31-34). Drugs are loaded onto the hydrogel during

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polymerization or cross-linking (page 10, lines 24 and 25). The hydrogel of Hennink are applied as microspheres of varying sizes (page 10, lines 26-34). See also examples 1-5 for preparation of hydrogels. The teachings of Hennink meet the limitations of the claims.

“When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not.” In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

***Claim Rejections - 35 USC § 103***

5. Claim 11 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hennink et al. (WO 98/00170, cited on form PTO-1449).

Applicants argue that Hennink does not render obvious claim 11 since Hennink does not disclose all the elements of claim 1.

6. Applicants' arguments filed 10/28/05 have been fully considered but they are not persuasive.

As discussed above, Hennink meets the limitations of the claim 1 (refer to response to applicants' argument under paragraph 3 of this communication). The rejection follows.

Hennink clearly teaches the instant hydrogel composition. Hennink teaches that increasing degree of substitution (DS) yields a more cross-linked network (page 9, lines 31-34). Hennink does not teach a degree of substitution of 3-25 as recited in instant claim 11. There is no comparable example to demonstrate that a degree of substitution of 3-25 provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a stereocomplex hydrogel that has appropriate degree of substitution since according to the teaching of Hennink degree of substitution is related to how cross-linked the polymer network is. One having ordinary skill in the art would have been motivated to prepare a

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stereocomplex hydrogel composition with a varying degree of substitution with the expectation of obtaining a hydrogel with the desired cross-linked network.

7. Claim 12 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Okihara et al. (J. Macromol. Sci. Phys. (1991) B30 (1 & 2)119-140, submitted on form PTO-1449).

Applicants argue that Okihara does not disclose all the limitations of claim 1 as was argued under 35 USC 102.

8. Applicants' arguments filed 10/28/05 have been fully considered but they are not persuasive because the claim 1 does not exclude organic solvent and same water soluble oligomers as are recited in the claims are disclosed by the prior art.

9. Claims 15-17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over De Jong et al. (Macromolecules, 1998, 31:6397-6402, provided by applicants on form PTO-1449) in view of Brannon-Peppas (Int. J. Pharm, 1995, 116:1-9, provided by applicants on form PTO-1449).

Applicants argue that hydrogels do not form in organic environment.

10. Applicants' arguments filed 10/28/05 have been fully considered but they are not persuasive.

The claims are directed to compositions. The oligomers are water soluble as directed by the claim 1 and claim 2 further defines the oligomers. These oligomers or at least some of the oligomers recited in claim 2 are some of the oligomers disclosed by the prior art. The difference between De Jong and the claims is that De Jong does not incorporate active agent in the stereocomplex and Brannon-Peppas makes up for that deficiency. See rejection below.

De Jong discloses preparation of stereocomplexes homo- or copolymers of D- and L-lactides and further discloses that stereocomplex formation is also observed in blends of L-

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lactide/ $\epsilon$ -caprolactone and D-lactide/ $\epsilon$ -caprolactone (abstract and page 6397). Synthesis of the stereocomplex begins with preparing the oligomer in the presence (2-(methoxyethoxy)ethanol (MEE)) initiator and stannous octoate catalyst (page 6399). De Jong does not teach incorporating active ingredient in the stereocomplex. However, Brannon-Peppas discloses that copolymers of polylactic acid are drug carriers (abstract). Regarding the sequence or preparing the drug containing hydrogel, selection of any order of the preparation steps in instant claims 15-17 is obvious in the absence of unexpected results showing that the order recited in the claims provides unusual results. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include an active ingredient in the hydrogel composition of De Jong since Brannon-Peppas teaches that lactide hydrogels can be drug carriers. One having ordinary skill in the art would have been motivated to include active agents in the lactide hydrogel formulation of De Jong with the expectation that the stereocomplex lactide hydrogel would serve as a carrier.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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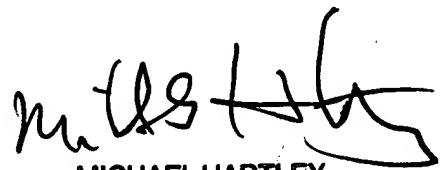
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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